NABI-HB- human hepatitis b virus immune globulin injection
ADMA Biologics, Inc

Hepatitis B Immune Globulin (Human) Nabi-HB Solvent Detergent Treated and Filtered

DESCRIPTION Hepatitis B Immune Globulin (Human), Nabi-HB, is a sterile solution of immunoglobulin (5 1 percent protein) containing antibodies to hepatitis B surface antigen (anti-HBs). It is prepared from plasma donated by individuals with high titers of anti-HBs. The plasma is processed using a modified Cohn 6 Oncley 9 cold-alcohol fractionation process1, 2 with two added viral reduction steps described below. Nabi-HB is formulated in 0.042-0.108 M sodium chloride, 0.10-0.20 M glycine, and 0.005-0.050 percent polysorbate 80, at pH 5.8-6.5. The product is supplied as a nonturbid sterile liquid in single dose vials and appears as clear to opalescent. It contains no preservative and is intended for single use by the intramuscular route only. Each plasma donation used for the manufacture of Nabi-HB is tested for the presence of hepatitis B virus (HBV) surface antigen (HBsAg), human immunodeficiency viruses (HIV) 1/2, and hepatitis C virus (HCV) antibodies. In addition, pooled samples of Source Plasma used in the manufacture of this product are tested by FDA licensed Nucleic Acid Testing (NAT) for HIV and HCV and found to be negative. Investigational NAT for hepatitis A virus (HAV) and HBV is also performed on pooled samples of all Source Plasma used, and found to be negative; however, the significance of a negative result has not been established. Investigational NAT for parvovirus B19 (B19) is also performed on pooled samples of all Source Plasma and the limit for B19 DNA in a manufacturing pool is set not to exceed 104 IU/mL. The manufacturing steps for Nabi-HB are designed to reduce the risk of transmission of viral disease. The solvent/detergent treatment step, using tri-n-butyl phosphate and Triton X-100, is effective in inactivating known enveloped viruses such as hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) 3. Virus filtration, using a Planova 35 nm Virus Filter, is effective in reducing some known enveloped and non-enveloped viruses4. The inactivation and reduction of known enveloped and non-enveloped model viruses were validated in laboratory studies as summarized in the following table

Table 1 Log Reduction of Test Viruses5 Test Virus					
	HIV	BVD	PRV	EMC	PPV
Model Virus:	HIV	HCV	HBV	Hepatitis A	PVB19
Envelope/Genome:	Yes/RNA	Yes/RNA	Yes/DNA	No/RNA	No/DNA
Manufacturing Step					
Precipitation of Cohn					
Fraction III	Greater than 5.9	3.6	3.7	4.4	3.9
Cuno Filtration	NT	NT	NT	Greater than 6.6	5.4
Solvent/Detergent	Greater than 4.2	Greater than 6.9	Greater than 6.4	NT	NT
Nanofiltration	Greater than 7.4	Greater than 6.9	Greater than 5.7	3.0	0.7
Cumulative	Greater than 17.5	Greater than 17.4	Greater than 15.8	Greater than 14.0	9.3

BVD Bovine Viral Diarrhea Virus PVB19 Parvovirus B19 NT not tested EMC Encephalomyocarditis Virus PPV Porcine Parvovirus Value not included in HIV Human Immunodeficiency Virus PRV Pseudorabies Virus cumulative clearance Product potency is expressed in international units (IU) by comparison to the World Health Organization (WHO) standard. Each milliliter (mL) of product contains greater than 312 IU anti- HBs. The potency of each milliliter of Nabi-HB exceeds the potency of anti-HBs in a U.S. reference hepatitis B immune globulin (FDA). The U.S. reference has been tested by Biotest Pharmaceuticals against the WHO standard and found to be equal to 208 IU/mL.

CLINICAL PHARMACOLOGY Hepatitis B Immune Globulin (Human) products provide passive immunization for individuals exposed to the hepatitis B virus as evidenced by a reduction in the attack

rate of hepatitis B following use6-9. Clinical studies10,11 conducted prior to 1983 with hepatitis B immune globulins similar to Nabi-HB indicate the advantage of simultaneous administration of hepatitis B vaccine and Hepatitis B Immune Globulin (Human). The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) advises that the combination prophylaxis be provided in certain instances of exposure based upon the increased efficacy found with that regimen in neonates12. Cases of hepatitis B are rarely seen following exposure to HBV in persons with preexisting anti-HBs. However, no prospective studies have been performed on the efficacy of concurrent hepatitis B vaccine and Hepatitis B Immune Globulin (Human) administration following parenteral exposure, mucous membrane contact, or oral ingestion in adults. Infants born to HBsAg-positive mothers are at risk of being infected with HBV and becoming chronic carriers13. The risk is especially great if the mother is also HBeAg-positive14. Studies conducted with hepatitis B immune globulins similar to Nabi-HB indicated that for an infant with perinatal exposure to an HBsAg-positive and HBeAg-positive mother, a regimen combining one dose of Hepatitis B Immune Globulin (Human) at birth with the hepatitis B vaccine series started soon after birth is 85-98percent effective in preventing development of the HBV carrier state15-17. Regimens involving either multiple doses of Hepatitis B Immune Globulin (Human) alone or the vaccine series alone have a 70-90percent efficacy, while a single dose of Hepatitis B Immune Globulin (Human) alone has 50percent efficacy18. Since infants have close contact with primary caregivers and they have a higher risk of becoming HBV carriers after acute HBV infection, prophylaxis of an infant less than 12 months of age with Hepatitis B Immune Globulin (Human) and hepatitis B vaccine is indicated if the mother or primary caregiver has acute HBV infection19. Sexual partners of HBsAg-positive persons are at increased risk of acquiring HBV infection. A single dose of Hepatitis B Immune Globulin (Human) is 75percent effective if administered within two weeks of the last sexual exposure to a person with acute hepatitis B19.

Pharmacokinetics Pharmacokinetics trials20 of Nabi-HB, Hepatitis B Immune Globulin (Human), given intramuscularly to 50 healthy volunteers demonstrated pharmacokinetic parameters similar to those reported by Scheiermann and Kuwert21. The half-life for Nabi-HB was 23.1 5.5 days. The clearance rate was 0.35 0.12 L/day and the volume of distribution was 11.2 3.4 L. Maximum concentration of Nabi-HB was reached in 6.5 4.3 days. The maximum concentration of anti-HBs and the area under the time-concentration curve achieved by Nabi-HB were bioequivalent to that of another licensed Hepatitis B Immune Globulin (Human) when compared in the same pharmacokinetics trial. Comparability of pharmacokinetics between Nabi-HB and a commercially available hepatitis B immunoglobulin indicate that similar efficacy of Nabi-HB should be inferred.

INDICATIONS AND USAGE Nabi-HB, Hepatitis B Immune Globulin (Human), is indicated for treatment of acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute HBV infection in the following settings: Acute Exposure to Blood Containing HBsAg Following either parenteral exposure (needlestick, bite, sharps), direct mucous membrane contact (accidental splash), or oral ingestion (pipetting accident), involving HBsAg-positive materials such as blood, plasma, or serum. Perinatal Exposure of Infants Born to HBsAg-positive Mothers Infants born to mothers positive for HBsAg with or without HBeAg12. Sexual Exposure to HBsAg-positive Persons Sexual partners of HBsAg-positive persons. Household Exposure to Persons with Acute HBV Infection Infants less than 12 months old whose mother or primary caregiver is positive for HBsAg. Other household contacts with an identifiable blood exposure to the index patient. Nabi-HB is indicated for intramuscular use only.

CONTRAINDICATIONS Individuals known to have had an anaphylactic or severe systemic reaction to human globulin should not receive Nabi-HB, Hepatitis B Immune Globulin (Human), or any other human immune globulin. Nabi-HB contains not more than 40 micrograms per mL IgA. Individuals who are deficient in IgA have the potential to develop antibodies against IgA and anaphylactic reactions. The physician must weigh the potential benefit of treatment with Nabi-HB against the potential for hypersensitivity reactions.

WARNINGS In patients who have severe thrombocytopenia or any coagulation disorder that would

contraindicate intramuscular injections, Nabi-HB, Hepatitis B Immune Globulin (Human), should be given only if the expected benefits outweigh the potential risks. Nabi-HB is made from human plasma. Products made from human plasma may contain infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. The risk that such products can transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current viral infections, and by inactivating and/or reducing certain viruses. The Nabi-HB manufacturing process includes a solvent/detergent treatment step (using tri-n-butyl phosphate and Triton X-100) that is effective in inactivating known enveloped viruses such as HBV, HCV, and HIV. Nabi-HB is filtered using a Planova 35 nm Virus Filter that is effective in reducing the levels of some enveloped and non-enveloped viruses. These two processes are designed to increase product safety. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other health care provider to Biotest Pharmaceuticals at 1-800-458-4244. The physician should discuss the risks and benefits of this product with the patient.

PRECAUTIONS General Nabi-HB, Hepatitis B Immune Globulin (Human), must be administered only intramuscularly for post-exposure prophylaxis. The preferred sites for intramuscular injections are the anterolateral aspect of the upper thigh and the deltoid muscle. If the buttock is used due to the volume to be injected, the central region should be avoided only the upper, outer quadrant should be used, and the needle should be directed anterior (i.e., not inferior or perpendicular to the skin) to minimize the possibility of involvement with the sciatic nerve22. The 50 healthy volunteers who received Nabi-HB in pharmacokinetic studies were followed for 84 days for possible development of anti-HCV antibodies. No subject seroconverted.

Drug Interactions Vaccination with live virus vaccines should be deferred until approximately three months after administration of Nabi-HB, Hepatitis B Immune Globulin (Human). It may be necessary to revaccinate persons who received Nabi-HB shortly after live virus vaccination. There are no available data on concomitant use of Nabi-HB and other drugs; therefore, Nabi- HB should not be mixed with other drugs.

Pregnancy Category C Animal reproduction studies have not been conducted with Nabi-HB. It is also not known whether Nabi-HB can cause fetal harm when administered to a pregnant woman or can affect a woman's ability to conceive. Nabi-HB should be given to a pregnant woman only if clearly indicated.

Nursing Mothers It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nabi-HB is administered to a nursing mother.

Pediatric Use Safety and effectiveness in the pediatric population have not been established for Nabi-HB. However, the safety and effectiveness of similar hepatitis B immune globulins have been demonstrated in infants and children12.

Geriatric Use Clinical studies of Nabi-HB did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

ADVERSE REACTIONS Fifty male and female volunteers received Nabi-HB, Hepatitis B Immune Globulin (Human), intramuscularly in pharmacokinetics trials20. The number of patients with reactions related to the administration of Nabi-HB included local reactions such as erythema 6 (12percent) and ache 2 (4percent) at the injection site, as well as systemic reactions such as headache 7 (14percent), myalgia 5 (10percent), malaise 3 (6percent), nausea 2 (4percent), and vomiting 1 (2percent). The majority (92percent) of reactions were reported as mild. The following adverse events were reported in the pharmacokinetics trials and were considered probably related to Nabi-HB: elevated alkaline phosphatase 2 (4percent), ecchymosis 1 (2percent), joint stiffness 1 (2percent), elevated AST 1 (2percent), decreased WBC 1 (2percent), and elevated creatinine 1 (2percent). All adverse events were mild in intensity. There were no serious adverse events. No anaphylactic reactions with Nabi-HB have been reported. However, these reactions, although rare, have been reported following the injection of

human immune globulins23.

OVERDOSAGE Although no data are available, clinical experience reported with other human immune globulins suggests that the only manifestations of overdose with Nabi-HB, Hepatitis B Immune Globulin (Human), would be pain and tenderness at the injection site.

DOSAGE AND ADMINISTRATION This product is for intramuscular use only. The use of this product by the intravenous route is not indicated. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. It is important to use a separate vial, sterile syringe, and needle for each individual patient, in order to prevent transmission of infectious agents from one person to another. Any vial of Nabi- HB, Hepatitis B Immune Globulin (Human) that has been entered should be used promptly. Do not reuse or save for future use. This product contains no preservative; therefore, partially used vials should be discarded immediately. Hepatitis B Immune Globulin (Human) may be administered at the same time (but at a different site), or up to one month preceding hepatitis B vaccination without impairing the active immune response to hepatitis B vaccine11. Acute Exposure to Blood Containing HBsAg Table 2 summarizes prophylaxis for percutaneous (needlestick, bite, sharps), ocular, or mucous membrane exposure to blood according to the source of exposure and vaccination status of the exposed person. For greatest effectiveness, passive prophylaxis with Hepatitis B Immune Globulin (Human) should be given as soon as possible after exposure, as its value after seven days following exposure is unclear12. An injection of 0.06 mL/kg of body weight should be administered intramuscularly as soon as possible after exposure and within 24 hours, if possible. Consult the hepatitis B vaccine package insert for dosage information regarding the vaccine. For persons who refuse hepatitis B vaccine or are known non-responders to vaccine, a second dose of Hepatitis B Immune Globulin (Human) should be given one month after the first dose12.

Table 2 Recommendations for Hepatitis B Prophylaxis Following Percutaneous or Permucosal Exposure 12 Exposed Person

Source	Unvaccinated	Vaccinated
HBsAg-positive	1. Hepatitis B Immune Globulin (Human) X1 immediately 2. Initiate HB Vaccine series	1. Test exposed person for anti-HBs 2. If inadequate antibody, Hepatitis B immune Globulin (Human) X 1 immediately plus either HB Vaccine booster dose or second dose of Hepatitis B Immune Globulin (Human) one month later
Known Source - High Risk for HBsAG-Positive	1. Initiate HB Vaccine series 2. Test source for HBsAG. If positive, Hepatitis B Immune Globulin (Human)1 X	1. Test source for HBsAG only if exposed is vaccine nonresponder; if source is HBsAG-Positive, Give Hepatitis B Immune Globulin (Human) 1 X immediately plus either HB vaccine booster dose or second dose of Hepatitis B immune Globulin (Human) one month later.
Known Source - Low Risk for HBsAG - Positive	Initiate HB Vaccine series	Nothing Required
Unknown Source	Initiate HB vaccine series	Nothing Required

Hepatitis B Immune Globulin (Human) dose of 0.06 mL/kg IM. See manufacturers' recommendation for appropriate dose. Less than 10 mIU/mL anti-HBs by radioimmunoassay, negative by enzyme immunoassay. Two doses of Hepatitis B Immune Globulin (Human) is preferred if no response after at least four doses of vaccine. Prophylaxis of Infants Born to Mothers who are Positive for HBsAg with or without HBeAg Table 3 contains the recommended schedule of hepatitis B prophylaxis for infants

born to mothers that are either known to be positive for HBsAg or have not been screened. Infants born to mothers known to be HBsAg-positive should receive 0.5 mL Hepatitis B Immune Globulin (Human) after physiologic stabilization of the infant and preferably within 12 hours of birth. The hepatitis B vaccine series should be initiated simultaneously, if not contraindicated, with the first dose of the vaccine given concurrently with the Hepatitis B Immune Globulin (Human), but at a different site. Subsequent doses of the vaccine should be administered in accordance with the recommendations of the manufacturer. Women admitted for delivery, who were not screened for HBsAg during the prenatal period, should be tested. While test results are pending, the newborn infant should receive hepatitis B vaccine within 12 hours of birth (see manufacturers' recommendations for dose). If the mother is later found to be HBsAg-positive, the infant should receive 0.5 mL Hepatitis B Immune Globulin (Human) as soon as possible and within seven days of birth; however, the efficacy of Hepatitis B Immune Globulin (Human) administered after 48 hours of age is not known10,19. Testing for HBsAg and anti-HBs is recommended at 12-15 months of age. If HBsAg is not detectable and anti-HBs is present, the child has been protected12.

Table 3 Recommended Schedule of Hepatitis B Immunoprophylaxis to Prevent Perinatal Transmission of Hepatitis B Virus Infection 19 Age of Infant

Administer	Infant born to mother known to be HBsAG-Positive	Infant born to mother not screened for HBsAG
First Vaccination	Birth (Within 12 hours)	Birth (Within 12 hours)
Hepatitis B Immune Globulin (Human)	Birth (Within 12 hours)	If mother is found to be HBsAG - positive, administer dose to infant as soon as possible, not later than 1 week after birth.
Second Vaccination	1 month	1-2 months
Third Vaccination	6 months	6 months

See manufacturers' recommendations for appropriate dose. 0.5 mL administered IM at a site different from that used for the vaccine. See ACIP recommendation. Sexual Exposure to HBsAg-positive Persons All susceptible persons whose sexual partners have acute hepatitis B infection should receive a single dose of Hepatitis B Immune Globulin (Human) (0.06 mL/kg) and should begin the hepatitis B vaccine series, if not contraindicated, within 14 days of the last sexual contact or if sexual contact with the infected person will continue. Administering the vaccine with Hepatitis B Immune Globulin (Human) may improve the efficacy of post exposure treatment. The vaccine has the added advantage of conferring long-lasting protection19. Household Exposure to Persons with Acute HBV Infection Prophylaxis of an infant less than 12 months of age with 0.5 mL Hepatitis B Immune Globulin (Human) and hepatitis B vaccine is indicated if the mother or primary caregiver has acute HBV infection. Prophylaxis of other household contacts of persons with acute HBV infection is not indicated unless they had an identifiable blood exposure to the index patient, such as by sharing toothbrushes or razors. Such exposures should be treated like sexual exposures. If the index patient becomes an HBV carrier, all household contacts should receive hepatitis B vaccine19.

HOW SUPPLIED Nabi-HB, Hepatitis B Immune Globulin (Human), is supplied as:

NDC Number Contents 59730-4202-1 a carton containing a 1 mL dose in a single-use vial (>312 IU) and package insert

59730-4203-1 a carton containing a 5 mL dose in a single-use vial (>1560 IU) and package insert

STORAGE

Refrigerate between 2 to 8 C (36 to 46 F). Do not freeze. Do not use after expiration date. Use within 6 hours after the vial has been entered.

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Manufactured by: Biotest Pharmaceuticals Corporation Boca Raton, FL 33487 U.S. License No. 1792 April 2008

Hepatitis B Immune Globulin (Human)

Nabi-HB

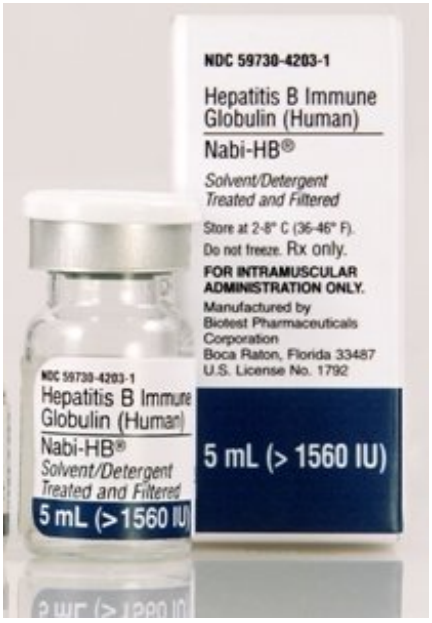
Solvent/Detergent Treated and Filtered

Store at 2-8 C (36-46 F)

Do not freeze. RX Only.

For intramuscular Administration only.

Manufactured by: Biotest Pharmaceuticals Corporation Boca Raton, FL 33487 U.S. License No. 1792 April 2008



NABI-HB

human hepatitis b virus immune globulin injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59730-4203
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HUMAN HEPATITIS B VIRUS IMMUNE GLOBULIN (UNII: XII270YC6M) (HUMAN HEPATITIS B VIRUS IMMUNE GLOBULIN - UNII:XII270YC6M)	HUMAN HEPATITIS B VIRUS IMMUNE GLOBULIN	1560 [iU] in 5 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCINE (UNII: TE7660XO1C)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59730-4203-1	5 mL in 1 VIAL; Type 0: Not a Combination Product	03/12/2010	09/30/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA103945	03/12/2010	09/30/2022

Labeler - ADMA Biologics, Inc (117213235)

Establishment

Name	Address	ID/FEI	Business Operations
ADMA Biologics, Inc		117213235	manufacture(59730-4203)

Revised: 12/2019 ADMA Biologics, Inc